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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,730	01/08/2002	Mie Takahashi	2001-1464A	5291
513 7590 12/10/2007 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			EXAMINER COUNTS, GARY W	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 12/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/937,730

Applicant(s)

TAKAHASHI ET AL.

Examiner

Gary W. Counts

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5, 12, 27, 31, 41, 45, 49, 53 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 12, 27, 31, 41, 45, 49, 53 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/06/07 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 5, 12, 27, 31, 41, 45, 53 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu (US 6,284,194) in view of Nanbu et al (US 6,130,055) or Uenoyama et al (US 5,856,117).

Chu discloses an analytical device and method of making the device. Chu teaches that the device comprises a porous reaction membrane and at least one receptor immobilized in a limited region (col 1, lines 40-50) (reaction layer and reactive components). Chu teaches applying a surfactant (surface active agent) to the reaction membrane and allowing to dry (col 1, lines 55-67). Chu teaches that drying can be performed by air drying at room temperature or by warm air with good ventilation (col 9, lines 30-43). Chu teaches the surfactant can be a surfactant such as polyoxyethylene (23), polyoxyethylene sorbitan monolaurate or polyoxyethylene sorbitan monooleate (col 8). Chu teaches that all or most of the surface (col 5, lines 27-32, col 9) is exposed to the surfactant.

Chu differs from the instant invention in failing to teach the surface active agent comprises a surface active agent having sugar in a hydrophilic part.

Nanbu et al disclose surfactants (surface active agent) used in bioassays. Nanbu et al disclose that the surfactant (surface active agent) can be polyoxyethylene

sorbitan monolaurate, polyoxyethylene sorbitan monooleate, or sucrose monolaurate (contains sugar in hydrophilic part) (col 3, lines 26-35). Nanbu et al teaches that the use of a surfactant improves the assay sensitivity.

Uenoyama et al disclose surfactants (surface active agents) used in bioassays. Uenoyama et al disclose that the surfactant (surface active agent) can be polyoxyethylene (23), polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monooleate, n-octyl-B-D-thioglucoside (sugar in hydrophilic part) or sucrose monolaurate (contains sugar in hydrophilic part) (col 3, line 59 – col 4, line 13). Uenoyama et al disclose that this surfactant improves the assay sensitivity.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute sucrose monolaurate surfactants (surface active agent) as taught by Nanbu et al for the surface active agent of Chu because Nanbu et al teaches that the use of a surfactant improves assay sensitivity. Further Chu teaches that polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate are surfactants which can be used in the analytical device and the method of making the device and Nanbu teaches the equivalence of polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate surfactants to sucrose monolaurate surfactants for their addition in bioassays and the selection to any known equivalents to replace the surfactants of Chu would be within the level of ordinary skill in the art and one of ordinary skill in the art would have a reasonable expectation of success using the surfactants (surface active agents) of Nanbu et al in the method and device of Chu.

It would have also been obvious to one of ordinary skill in the art at the time the invention was made to substitute the n-octyl-B-D-thioglucoside (sugar in hydrophilic part) or sucrose monolaurate surfactants (surface active agent) as taught by Uenoyama et al for the surface active agent of Chu because Uenoyama et al teaches that the use of a surfactant improves assay sensitivity. Further Chu teaches that polyoxyethylene (23), polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate are surfactants which can be used in the analytical device and the method of making the device and Uenoyama et al teaches the equivalence of polyoxyethylene (23), polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate surfactants to sucrose monolaurate and n-octyl-B-d-thioglucoside surfactants for their addition in bioassays and the selection to any known equivalents to replace the surfactants of Chu would be within the level of ordinary skill in the art and one of ordinary skill in the art would have a reasonable expectation of success using the surfactants (surface active agents) of Uenoyama et al in the method and device of Chu.

With respect to claims 41 and 45 as recited in the instant claims. Chu teaches that drying can be performed by warm air in good ventilation. Therefore, Chu teaches drying moving air (wind) and thus Chu teaches wind drying as recited in the instant claims.

6. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chu in view of Nanbu et al or Uenoyama et al as applied to claims 5, 12, 27, 31, 41, 45, 53 and 60 and further in view of Iwata et al (US 5,912,139).

See above for teachings of Chu, Nanbu et al and Uenoyama et al.

Chu, Nanbu et al and Uenoyama et al differ from the instant invention in failing to teach the reactive layer is dried by freeze drying.

Iwata et al disclose producing a test strip by impregnating a carrier with a solution comprising components. Iwata et al disclose that the impregnated carrier is then dried by freeze drying (col 6, lines 48-59). Iwata et al disclose that the components can be surfactants (col 6, lines 3-14 and col 10, lines 10-22). Iwata et al disclose that freeze drying thoroughly removes water from the carrier (col 6, line 53). Iwata et al disclose that this provides for a test strip, which provides high sensitivity and high accuracy measurement and excellent storage stability (abstract & col 2, lines 22-43).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate freeze drying as taught by Iwata et al into the modified method of Chu because Iwata et al teaches that freeze drying thoroughly removes water from the carrier and Iwata et al also teaches that this provides for a test strip which provides high sensitivity and high accuracy measurement and excellent storage stability.

Response to Arguments

7. Applicant's arguments filed November 6, 2007 have been fully considered but they are not persuasive.

Applicant argues that the Examiner is attempting to employ an "obvious to try" rational, i.e. to try the various surfactants of Nanbu et al and Uenoyama et al in the composition of Chu. Applicant directs the Examiner's attention to KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727 (U.S. 2007) and states that in KSR, the Supreme Court

addressed the "obvious to try rationale, which has often been rejected by the Court of Appeals for the Federal Circuit. Applicant states that the Supreme Court did not indicate that "obvious to try" is always an appropriate rationale for proving obviousness. On the contrary, the Court stated, "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. Applicant states that Chu, Nanbu et al. and Uenoyama et al references teach many surfactants and that given the very large number of known surfactants, it cannot be said that picking and choosing from the large number would be considered a finite number of identified predictable solutions. This is not found persuasive because the Examiner is not employing an "obviousness to try" rationale. Rather, the rationale that simple substitution of one known equivalent, element for another to obtain expected results. As stated above Chu teaches that polyoxyethylene (23), polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate are non-ionic surfactants which can be used in the analytical device and the method of making the device, and both Nanbu et al and Uenoyama et al teach that sucrose monolaurate (non-ionic surfactant) is an equivalent reagent to those disclosed by Chu. Thus, the surfactants that are considered equivalent are obtained from the same family of surfactants (non-ionic surfactants).

With respect to applicants arguments that the references of Nanbu et al and Uenoyama et al teaching an infinite number of surfactants. This is not found persuasive because the surfactants disclosed by Nanbu et al and Uenoyama et al would not be

considered an infinite number of surfactants because as stated above Chu teaches that polyoxyethylene (23), polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate are non-ionic surfactants which can be used in the analytical device and the method of making the device, and both Nanbu et al and Uenoyama et al teach that sucrose monolaurate (non-ionic surfactant) is an equivalent reagent to those disclosed by Chu. Thus, Chu is teaching non-ionic surfactants and the secondary references of Nanbu et al and Uenoyama et al are also teaching non-ionic surfactants and therefore one of ordinary skill in the art would select the non-ionic surfactants of the Nanbu et al and Uenoyama et al references as obvious substitutes for the non-ionic surfactants of Chu. Further, as stated in the previous office actions and above both Nanbu et al and Uenoyama et al teach that surfactants provide the advantage of improving assay sensitivity which is noted as being the same as the advantage disclosed by Applicant on page 10, lines 12 and 13 "higher sensitivity" (applicant's specification). Thus, the surfactants are considered equivalents because the surfactants are within the same family of non-ionic surfactants and provide the same purpose of improving assay sensitivity and are provided for use in bioassays. Thus, one of ordinary skill in the art would have a reasonable expectation of success substituting surfactants such as taught by Nanbu et al and Uenoyama et al for the surfactants of Chu.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gary Counts
Examiner
Art Unit 1641
December 5, 2007


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